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A randomised controlled trial to evaluate the clinical and cost effectiveness of breastfeeding peer support groups in improving breastfeeding initiation, duration and satisfaction

Submission date
19/12/2006

Recruitment status
No longer recruiting

Registration date
21/02/2007

Overall study status
Completed

Last Edited
03/02/2009

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.abdn.ac.uk/BIG/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZH/4/156

Study information

Scientific Title

Acronym
The BIG Trial

Study objectives
1. To compare clinical and cost effectiveness of a policy to provide breastfeeding support groups with usual care (internal control) and non-participating areas of Scotland (external control)
2. To compare before and after breastfeeding rates at six to eight weeks between intervention and control
3. To compare womens breastfeeding satisfaction between intervention and control
4. To measure the costs of the intervention to the health service and parents of each additional percentage point change in breastfeeding prevalence at six to eight weeks
5. To examine implementation processes using a qualitative case study approach

Ethics approval required
Old ethics approval format

Ethics approval(s)
Metropolitan MREC approval gained on the 26th July 2004 (ref: 04/MRE11/28)

Study design
Randomised controlled trial and qualitative case-studies

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Breastfeeding

Interventions
14 clusters of GP practices will be randomised to intervention or control. Intervention areas will be asked to double their existing number of breastfeeding groups and set up a minimum of two new breastfeeding groups. Groups will:
1. Be for women and their children
2. Be held weekly
3. Invite pregnant women and breastfeeding mothers
4. Have a health professional group facilitator
5. Be woman-centred with at least 50% of time social and interactive.

Area group facilitators will meet with women and voluntary organisation representatives every six to eight weeks for support and reflective practice. A group resource pack and a training day will be provided.

Control areas will provide usual care with no new breastfeeding group activity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Any breastfeeding (exclusive or partial) at six to eight weeks for two years pre-study and two study years (National Child Health Surveillance Programme data).

Secondary outcome measures
1. Any breastfeeding at birth (National Child Health Surveillance Programme data).
2. Any breastfeeding at seven days (Guthrie data).
3. Any breastfeeding at eigh to nine months (National Child Health Surveillance Programme data).
4. Womens' satisfaction using the Maternal Breastfeeding Evaluation Scale.
5. Social support using The Duke-UNC Functional Social Support Questionnaire.
6. Knowledge of and attendance at any birth related groups.
7. Qualitative case studies to examine variations and implementation processes.
8. NHS costs and the costs and benefits to women.

Overall study start date
01/10/2004

Completion date
30/09/2007

Eligibility

Key inclusion criteria

1. Clusters of General Practitioner (GP) practices collecting National Child Health Surveillance Programme data
2. Any pregnant women or breastfeeding mothers with babies less than eight months old can participate in breastfeeding groups set up by intervention areas

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
14 clusters of GP practices

Key exclusion criteria
1. Clusters of GP practices that do not collect National Child Health Surveillance Programme data
2. Any woman identified by health professionals as having a severe medical or mental health problem which could be detrimental to other group participants and/or their babies

Date of first enrolment
01/10/2004

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Rural Health
Inverness
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IV2 3BL

Sponsor information

Organisation

University of Aberdeen (UK)

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Sponsor type
Not defined

Website
http://www.abdn.ac.uk/crh/

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Scottish Executive Health Department, Chief Scientist Office (UK) (ref: CZH/4/156)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	recruitment results	01/05/2007	Yes	No
Results article	results	30/01/2009	Yes	No